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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,025	11/21/2003	Elliot Lorne Chaikof	133-02	3169
23713 7590 08/14/2008 GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301				
EXAMINER NOAKES, SUZANNE MARIE				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
08/14/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/720,025

**Applicant(s)**

CHAIKOF ET AL.

**Examiner**

SUZANNE M. NOAKES

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 12-32,35,36 and 41-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,33,34 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01/24/2004;07/01/2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 2-11, 33, 34 and 37-40 in the replies filed on 08 May 2008 (which updates the responses of 01/24/2008 and 05/07/2007) are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 1 links inventions I, III, IV, XVI-XIX and XXIII-XXVIII and thus claim 1 will be examined with Group I as noted above.
2. Claims 12-32, 35, 36 and 41-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse as noted above.
3. Upon further reconsideration, the restriction requirement made between SEQ ID NO: 11 and SEQ ID NO: 12 in claims 4 and 6-8 is hereby withdrawn. Likewise, the restriction requirement between SEQ ID NOs: 23-25 in claim 9 is hereby withdrawn and the specified sequences are rejoined and will be examined fully.

### ***Status of the Claims***

4. Claims 1-76 are pending and claims 12-32, 36, 36 and 41-76 are withdrawn from consideration as noted above. Claims 1-11, 33, 34 and 37-40 are subject to Examination on the merits.

***Priority***

5. Acknowledgment is made of applicant's claim for foreign priority based on an applications filed in Canada, Japan and Australia on 01/29/2003, 04/01/2003 and 08/27/2003, respectively. It is noted, however, that applicant has not filed certified copies of the foreign applications as required by 35 U.S.C. 119(b).

***Information Disclosure Statement***

6. The information disclosure statements (IDS) submitted on 01 July 2004 and 21 January 2004 have been considered by the examiner. See initialed and signed PTO-1449's. It is noted that US patent 5,556,632 as said patent has been withdrawn and is no longer publicly available.

***Specification***

***Compliance with Sequence Rules***

7. The sequence listing, filed in computer readable form (CRF) and paper copy on 21 November 2003, has been received and entered. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

The specification contains various amino acid sequences without corresponding sequence identifiers on p. 7, paragraph 20.

\* If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 8, 11, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright and Capello (Adv. Drug Deliv. Rev., Oct. 2002, 54:1057-73 – cited on IDS from 1/21/04).

Wright and Capello teach synthetic protein copolymers of the construction AB and BAB, wherein A is a hydrophilic block and B is a hydrophobic block. Various representative B and A blocks are taught in Table 2, p. 1060. It is noted that the B blocks are of the form: [VPAVG(IPAVG)<sub>4</sub>]<sub>16</sub>. Since claim 1 open comprising language, it is deemed that this sequence is encompassed in the instant SEQ ID NO: 12 (and is SEQ ID NO: 11). The copolymers form microparticles (e.g. self-assembled gels – see Figure 7) and also have inverse transition temperatures at about 25°C (see p. 1068, 1<sup>st</sup> column, 1<sup>st</sup> paragraph).

10. Claims 1-3, 5, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright et al. (Adv. Funct. Materials, Feb. 2002, 12:149-54 – cited on IDS of 1/21/04).

Wright et al. teach synthetic protein copolymers of the construction AB and BAB, wherein A is a hydrophilic block and B is a hydrophobic block. Scheme 1 on p. 149 comprises two different copolymers of the BAB form wherein copolymer 1 *comprises* SEQ ID NO: 18 of claim 5 as the middle hydrophilic block. Both copolymers display transition temperatures at about 21 and 23°C, respectively (see p. 150, 1<sup>st</sup> column, last paragraph and Figure 3). Both copolymers form microparticles having micellar particles (e.g. spherical shape)-(see p. 152, last paragraph).

11. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Capello et al. (J. of Controlled Release, 1998, 53:105-117).

Capello et al. teach a synthetic protein copolymers which possess one hydrophobic block of GVGVP and one hydrophilic block of GAGAGS (see p. 106, col. 1, 2<sup>nd</sup> paragraph) and termed ProLastins. See also Tables 1 and 2, pp. 106-107.

12. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Adv. Materials, 2000, 12(15):1105-10 – cited on IDS from 1/21/04).

Lee et al. teach synthetic protein copolymers which comprise a hydrophilic block and a hydrophobic block (see Scheme 1, Copolymer 1, p. 1106). The copolymer is capable of being elongated 'upto about 14 times initial length', meaning that it can be elongated even twice and that is "upto" 14.

### ***Conclusion***

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne M. Noakes/  
Patent Examiner, Art Unit 1656  
11 August 2008